

SPL ER/DL SubTeam Teleconference with FDA Drug Listing and Import March 30, 2011 Meeting Minutes

FDA participants:

- DRLS - Paul Loebach
- CBER - Vada Perkins
- CVM - Charise Kasser
- Import - Huascar Batista
- SPL Group - Lonnie Smith

Key:

Agenda and questions are in black text.

FDA Participant responses and additional meeting questions/discussion are in red text

CVM post meeting notes are highlighted in blue

Additional post meeting questions /responses are in yellow highlights.

Topics of discussion:

1. New Marketing Categories - Manufactured exclusively for Private Label Distributors (PLD)

Several new marketing categories were recently published.

- APPROVED DRUG PRODUCT -- MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR
- OTC MONOGRAPH DRUG PRODUCT -- MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR
- UNAPPROVED DRUG PRODUCT -- MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR

How /when are these intended to be used? Please provide specific examples.

- a. Please provide specific scenarios in which each marketing category could/should be used?
- b. What document type (s) are these intended to be used with?
- c. What information would be required for SPL that use these marketing categories?
 - content of labeling?
 - principal display panel or other packaging graphics (jpg)?

Response/Discussion:

- In the old paper system, CDER required everyone in the supply chain to drug list. With the new electronic guidelines, we've tried to implement a process where the information was captured in 1 SPL to be submitted by the PLD. We have found that this isn't providing all the necessary information. Thus we are now recommending that both the manufacturers and the PLDs drug list their products.
- These marketing categories are to be used specifically for manufacturers who don't market product, but manufacture product exclusively for private label distributors.
- What doc types can these marketing categories be used with?
 - Human prescription drug or Human OTC
- What information is required to be included in the SPL?
 - Supply chain, Principal Display Panel/image (PDP), drug listing data elements (DLDE).
 - The SPL does NOT require content of labeling.
 - APPROVED DRUG PRODUCT – must include NDA/BLA/ANDA/AADA information
 - OTC Monograph Drug Product - include Monograph information
- The final marketer / PLD is expected to drug list their products using their own labeler code/ NDCs

Additional questions/discussion:

- If a company makes product that goes to 3 PLDs, do they have to submit 3 different SPLs?
 - Response: If a company produces a product for multiple private label distributors, the company would prepare a single SPL, with details about each of the private label distributors and PDP's for each of the distributors products.
- What information will be posted to public web sites?
 - Response: None. The NDC information will not be included in the NDC Directory, and nothing will be released to DailyMed.

2. Marketing Categories: “Bulk Ingredient” and “Drug for Further Processing”

- a. Where/how are these intended to be used? How do these relate to the newly published categories in the question above?

Response/Discussion:

Bulk ingredient:

- API - 100% purity.
- Other material that is not packaged for final use/ sale.

Drug for Further Processing:

- Any non-100% pure product in the manufacturing/packaging process.
- Use this marketing category for unfinished products or intermediates
 - Drug that is not 100% pure.
 - Drug not ready for human use yet, eg.
 - i. not packaged for final use
 - ii. needs further processing.
- SPL does not include content of labeling....only shipping label.
- Not included in NDC directory and/or Daily Med.

- b. Does the listing of the final processed product need to reference the “drug for further processing” source NDC?

Response/Discussion:

Yes, this will be helpful. Include the source NDC.

The source NDC was created for repackers/relabelers who do not know the supply chain.

- c. “Drug for Further Processing:” Please provide examples. Are the ones listed below valid?
- Semi-pure API that is requires further purification to API **yes**
 - API that isn’t 100% pure (e.g. Acetaminophen 90% granulation) **Yes**
 - Bulk drug product (drums of tablets, capsules, nude vials, powder for injection) that requires further packaging and labeling **Yes**

Response/Discussion:

All the examples provided above are valid examples of “Drug for Further Processing”

Pre- API does NOT have to be drug listed.

Manufacturers further down in the supply chain will have to include the source NDC.

- d. Will SPL using this category be posted on Daily Med? **No**
- Potential concern: The SPL subteam doesn’t think non-finished products should appear on Daily Med or listed in the NDC directory, as downstream users and direct consumers search both these locations for patient-available information.

Response/Discussion:

The NDC information will not be included in the NDC Directory, and nothing will be released to DailyMed.

Post meeting: Additional follow-up questions:

- How do we handle API and bulk tablets within the same company.....do we have to put in source NDC codes for the manufacturer????
 - This is not required, but it is helpful. It makes it easier for FDA to track the supply chain.

- Will these SPL files be available in the access database to make sure that the files processed correctly.
 - They are not publicly available.
 - FDA needs them for tracking purposes.
 - Contact eDRLS@fda.hhs.gov for verification that it is in their internal database.

- *****

3. At what point is a product drug listed?

When is a drug truly considered to be drug listed?

Timing options include:

- Received by OC , validated, and available in the access data repository
 - Response: It may be, but not necessarily.
- Posted on Daily Med
 - Response: It may be, but not necessarily.
- Added to the NDC directory
 - Response: It may be, but not necessarily. It can be removed, if a deficiency is found.

Response/Discussion CDER:

- FDA joke: 'it's listed when we say it's listed'
- Real answer: it is drug listed when the information is complete and accurate – both the manufacturing registration information and the drug listing information.
- If a registration or listing passes automated validation, but is incomplete or inaccurate, DRLS will contact the submitter.
- Is something "listed" even though it isn't published on the NDC directory? ie between bimonthly postings?
 - If the product is adequately listed, even if you don't see it in the NDC directory, it is most likely listed. You can contact the DRLS Team in between Directory updates for the status.
- At any time if DRLS finds a deficiency, DRLS will contact the firm requesting to send complete and accurate registration and listing information. DRLS will put the drug product in pending status until the information is corrected and resubmitted by firm. This will result in the NDC code for the drug disappearing from the Directory until the complete and accurate information is received.
- How long between the time of submission and the time that a file could be considered adequate?
 - There is no firm answer. It's the firm's responsibility to make sure submitted information for registration and listing is complete and accurate. DRLS Team is available to answer your questions on registration and listing issues you might have on your submission.

Response/Discussion CVM – Veterinary Products:

Post meeting note:

Veterinary drugs are **not** in the NDC Directory **only human drugs**. For veterinary drugs, they are considered drug listed when received by OC, validated, and available in the access data repository and when posted to Daily Med.

Additional questions:

- What is considered adequate?
 - Refer to Section 510(i) of the act.
- Can you give us examples of situations that would be considered inadequate?
- Registration information: Example, the listing for any drug (new or old listing) is inadequate when the name of the domestic importers are not included in the foreign manufacturers registration.
- NDC Directory updates – what if a sponsor submits drug listing and still doesn't see the new NDC in the NDC Directory – ie after several months.
 - Contact DRLS at eDRLS@fda.hhs.gov
- If you put in a future market end date, will the product be listed until the end marketing date?
 - Yes

- When there are just minor changes in the SPL, is the listing reviewed the same way that a new listing?
 - Yes. Whenever you send in an update, the new version supercedes the previous version.

4. Delisting pack sizes

Please confirm the process for delisting pack sizes? Currently we delist them by simply just removing the pack size from the SPL?

- Is there an automatic comparison to the previous/current version? If not, what triggers the DRLS staff to delist the pack size? How does it get removed from the NDC directory?

Response/Discussion:

- Whenever you submit an updated SPL, the new version will supercede the previous version in the system. So NDC changes should be picked up.
- If a pack size is left off, it will be discontinued and won't appear in the NDC directory.
- For deletions of drug products, be sure to also include the status change and end market date.
- For paper-only listed products (ie products that have not been updated electronically)- you can delist them by sending an email to the eDRLS email.
 - Please provide complete product information, so that DRLS staff can accurately identify the product: Tradename, generic name, strength, pack size, NDC code.
 - UPDATE: With publication of the new NDC Directory in Jun 2011, the NDC directory file which includes the old paper-based products will most likely NOT be updated.
 - Note: This will NOT remove the SPL from Daily Med.
- This method of delisting can result in inadvertent mistakes. Example: If you have a listing that has multiple product NDCs, AND you submit an update that inadvertently doesn't include all product codes or package sizes from previous listings, the products omitted from the listing may disappear. To correct this, you will need to submit an update electronically that includes all the NDC codes.
 - Note: FDA is looking into a way to flag these.

5. Deleting multiple listings from the DFARS site

There are currently establishments (or multiple listings of the same establishment) in the DFARS list with date prior to 2010. How do we remove these old listings?

Response/Discussion:

- DFARS system is a mix of paper and electronic listings. Internal debate is occurring within FDA on whether to go ahead and remove the older/paper versions.
- The DFARS site is only supposed to contain the most recent registration information. If there are incorrect listings on the DFARS site, definitely contact the SPL Coordinator.
- Two ways to correct a record:
 - If a site was registered electronically in 2009 or 2010 by SPL, send in an “out of business” SPL.
 - If an establishment is in DFARS from the old paper system, send an email to eDRLS@fda.hhs.gov and the SPL Coordinator. Please send in as much information as possible (ie FEI number), so that DRLS staff can identify the right record.
- DRLS emphasizes the importance of industry keeping their own records up to date.

Additional questions:

- Why would there be multiple listings for the same site for different years? Or old sites that are out of business.
 - For some reason, the system doesn’t recognize the site as the same. There is probably a minor difference in the company name or address.
 - If registration information on the two submissions (paper based and SPL) do not match 100%, the system might recognize the SPL submission as a new site, and therefore it appears on the DFARS twice. Make sure you follow the SPL instructions closely to avoid duplicates in DFARS.
 - If your company is having this issue, check the FEI numbers.
- Who should a company contact to find out which FEI number is correct? Contact either local FDA district site, or contact DRLS for help in pointing you in the right direction. Please update your registration record and let DRLS know if your FEI number is different from what you submitted with your registration information. This has an impact on the possible inspection processes and needs to be captured in your registration record.
- Note: A clean-up activity is ongoing to reconcile or merge FEI records.
- Note: the DUNS number validation can help prevent this problem in the future.
- Note: If you contact DRLS about a different firm, they can’t provide information about the other firm’s information, because it is considered confidential. DRLS can only release public information. Suggest that you contact the CM for the correct information.

6. Inactive Ingredients

Recently, OTC sponsors have started receiving validation errors because all inactive ingredients are not included in the drug listing data. Previous to electronic drug listing, OTC products were not required to provide this information in the drug listing forms.

Question: Would you provide a citation or reference that includes the requirement for all inactive ingredients to be included in drug listing?

We have identified the following relevant sections of the CFR:

- Sec. 207.25 Information required in registration and drug listing.
 - Does not specify nor exclude inactive ingredient listing
- Section 207.31 Additional drug listing information
 - (b) It is requested but not required that a qualitative listing of the inactive ingredients be submitted for all listed drugs in the format prescribed in Form FDA-2657 (Drug Product Listing).
- PART 201 – LABELING Subpart C--Labeling Requirements for Over-the-Counter Drugs
Sec. 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.
(c) Content requirements.
(8) "Inactive ingredients", followed by a listing of the established name of each inactive ingredient. If the product is an OTC drug product that is not also a cosmetic product, then the inactive ingredients shall be listed in alphabetical order. If the product is an OTC drug product that is also a cosmetic product, then the inactive ingredients shall be listed as set forth in 701.3(a) or (f) of this chapter, the names of cosmetic ingredients shall be determined in accordance with 701.3(c) of this chapter, and the provisions in 701.3(e), (g), (h), (l), (m), (n), and (o) of this chapter and 720.8 of this chapter may also apply, as appropriate. If there is a difference in the labeling provisions in this 201.66 and 701.3 and 720.8 of this chapter, the labeling provisions in this 201.66 shall be used.

Response/Discussion:

- FDA is encouraging companies to do the right thing and to include information on inactive ingredients. Most companies are complying with this.
- A validator is in place to check for this. However, it can be overridden. If this is a problem for a sponsor, please send an email to Lonnie Smith at spl@fda.hhs.gov requesting an override.
- Inactive ingredients can be marked as confidential.
- This only applies to OTC products for now.

7. Business Operation Terms

SPLs are failing validation because contract manufacturer (CM) and private label distributor (PLD) are using different business operations in their listings.

- a. Would you please provide definitions and guidelines for business operation terms so that it is clear what business operation terms to include in drug establishment and drug listing submissions?
- Confusion over :
 - the definitions of similar terms, e.g., pack versus re-pack, label versus re-label.
 - what manufacturing sub-operations are included within the overarching term of manufacture and API manufacture.
 - We have received consult from FDA that the term “manufacture” can be used in Drug Establishment Registration (DER) and drug listings when a site does the complete manufacturing operation: drug product, packing, and labeling.
 - Is analysis considered a sub-term of “API manufacture” and “manufacture”?
 - Does the term ‘manufacture’ encompass all of the component operations?
 - Scenarios:
 - A CM includes the term “re-pack” in its DER – because they do re-packing (for secondary suppliers of the product). However they also do the initial packing for principle manufacturers. The SPL fails when the PLD includes the valid term “pack” – which is the actual operation that is being done for that product.
 - A manufacturer (or CM) includes the term “manufacture” in their DER for their establishment – because the facility does all manufacturing steps (drug product manufacturing, packing, and labeling). However for a specific product, this site only does packing and labeling. The SPL for this product includes only the terms “pack” and “label” for this establishment. The SPL for this product fails validation. [[Note: the PLD is hesitant to include the term “manufacturer” for this establishment because they don’t want FDA to inspect this establishment for drug product manufacturing.]]
- b. Can validation programs be modified to allow flexibility for the situations outlined above?
- Response/Discussion:**
No – the information should match. If there are discrepancies between the DER and DL, sponsors should contact the contract manufacturers to resolve this and reach consistency.
- c. Having information available about the business operations that have been registered for an establishment would be very helpful to sponsors and vendors filing drug listings. We have heard that these have not been made readily available in the past because there may be concerns about confidentiality, and also concerns about making large numbers of DUNS numbers available publicly via the FDA sites. Is there any possibility of making these available in some way at some point in the future? For instance, perhaps this could be made available via a search functionality (put in DUNS number, retrieve business operations) without the ability to download the complete list and without the ability to browse the entire list.

Response/Discussion:

FDA understands the issue. They are still not sure if they can publish this info or not as it may be confidential. DRLS will look into it, but it won’t be resolved soon.

8. Drug listings by a Manufacturer versus a Private Label Distributor (PLD)

If a PLD chooses to drug list a product using its own labeler code, under what circumstances is the manufacturer required to drug list the product under its own labeler code?

Background:

Sponsors' current understanding is that drug listing for the final drug product can be managed in one SPL submitted by the PLD – with all relevant manufacturers/establishments included in the final SPL. The manufacturer does not have to submit a separate SPL for drug listing (under a separate labeler code) as long as (1) they sell the product to only one PLD, and (2) the PLD includes their establishment information (DUNS and business operation) in the final product drug listing SPL.

Sponsors are having product (API and/or drug product) detained while importing the product, and they are getting questions about drug listing by the manufacturing site.

Key Concerns from Pharma:

- If both PLD and CM drug list under separate labeler codes, there would be duplicate listings posted on DailyMed – one for the PLD and one for the manufacturer.
 - Viewers and downstream users would not be able to differentiate between the SPL from the multiple labelers.
 - The SPLs could easily be out of sync. Changes to SPL for label changes must be submitted within 14 days by the NDA holder. There may be a lag between when the NDA holder (PLD) updates the drug listing and when the manufacturer submits the updated SPL.
- Confidentiality of contract manufacturers (CM).
 - There are situations in which the PLD would not want to disclose the identity of the CM. This is currently managed by marking the CM as confidential in the SPL.
 - If the CM has to drug list under their own labeler code, the CM would be included as the labeler for the product.

Thus we would like to clarify the current guidelines on who needs to submit SPL for drug listing – especially as it relates to importing the API and/or drug product. Several scenarios are outlined below. Please comment on who needs to submit SPL for drug listing for the scenarios below:

Response/Discussion by DRLS:

- All of the scenarios relate to the question of whether both the manufacturer and the PLD need to submit drug listing files. If your establishment is listed separately from the PLD, then you are required to list.
- Generally, if a product is manufactured within the same parent company, then it is considered an interplant transfer, and the drug listing can be done within one SPL drug listing submission.
 - Confusion sometimes arises when there is a different name and address.
 - The different name/address adds time, labor, and confusion at the point of entry and may cause the local FDA office to issue a detention.
- If you are manufacturing a product for a PLD, then you can use the new marketing categories discussed in question 1. The submission does not have to include COL.

Response/Discussion by Import/Export:

- We need information about each manufacturer, packager, and labeler with a unique function in the supply chain. To have a complete supply chain, each establishment must be listed separately, even if it is headquartered in the US.
- PLDs are not considered registrants.
- Even if companies are part of the same parent, they are not exempt from listing. The import group sees the manufacturers as individual entities, not the same company. Different manufacturing sites are individual entities.

Response/Discussion CVM – Veterinary Products:

Post meeting note:

CVM products are managed differently from human products, because user fees are directly connected to drug listing. Drug listing for the final veterinary drug product can be managed in **one SPL** with all relevant manufacturers/establishments included in the **final SPL**. CVM's stance on who needs to submit SPL for drug listing has been that the ultimate responsibility falls on the sponsor.

Scenario A: A major pharmaceutical company manufactures a product at one of the company's wholly owned manufacturing establishments. The finished product is shipped to one of the company's distribution centers in the US, and the product is sold by the company. Our current understanding of the electronic drug listing process:

- Drug listing can be done using 1 SPL file submitted by the pharmaceutical company as the PLD. All establishments involved in the supply chain are included in the SPL (possibly marked as confidential).

Response/Discussion by Import:

When manufacturing/marketing is done within the same company, the movement from the manufacturing site to the distribution center is considered an interplant transfer. Nothing has entered commercial distribution. Thus, the drug listing can be accomplished by 1 SPL /drug listing.

Scenario B: A major pharmaceutical company (PLD) contracts with a CM (**in the US**) to have them manufacture a product for them. The finished product is shipped to one of the company's facilities (or to another CM for finishing, if necessary), and the product is sold in the US by the PLD company. Our current understanding of the electronic drug listing process:

- Drug listing can be done using 1 SPL file submitted by the pharmaceutical company as the PLD. All establishments involved in the supply chain are included in the SPL (possibly marked as confidential). The CM does not have to submit a separate drug listing.

Response/Discussion by FDA/Import:

When manufacturing is done by a CM for a PLD, listings for both the CM and the PLD must be submitted.

- The PLD submits a full SPL (with Content of Labeling , COL) and the SPL is posted on Daily Med. Or the CM has to drug list the product on their behalf –using the PLD's NDC number and COL.
- The CM creates an SPL using one of the new marketing categories described in question 1 – “XXX Drug Product – Manufactured exclusively for Private Label Distributor. “ No COL is provided.

If the CM also markets the product under its own labeler code, they would submit a complete SPL for drug listing using their own product/NDC code(s). They do not have to submit a separate SPL using the marketing category – “XXX Drug Product – Manufactured exclusively for Private Label Distributor. “

Scenario C: A major pharmaceutical company (PLD) contracts with a CM (**outside the US**) to have them manufacture (including packing and labeling) a product for them. The finished product is shipped/imported into the US to one of the company's facilities (or to another CM for finishing, if necessary), and the product is sold in the US by the company (PLD).

Our current understanding of the electronic drug listing process:

- Drug listing can be done using 1 SPL file submitted by the pharmaceutical company as the PLD. All establishments involved in the supply chain are included in the SPL (possibly marked as confidential). The CM does not have to submit a separate drug listing.

Response/Discussion:

Drug listings for both the CM and the PLD must be submitted– see explanation in Scenario B.

Scenario D: A pharmaceutical company (PLD) buys a bulk material (e.g., API, in process API, bulk tablets, capsules, vials, etc) from a manufacturer (**inside or outside the US**). The manufacturer sells this product to multiple customers – i.e. they do not manufacture this product exclusively for one company in the US. The product is then finished (by either the PLD or another CM) and sold by the PLD.

Our current understanding of the electronic drug listing process:

- The CM drug lists the material using
 - document type of “bulk ingredient” and
 - marketing category of either “bulk ingredient” or “drug for further processing”
- The PLD drug lists the finished product. All establishments involved in the supply chain are included in the SPL (possibly marked as confidential).

Response/Discussion:

- This is correct. Drug listings must be submitted by both the CM and the PLD – see explanation in Scenario B.

Additional discussion during the teleconference:

- We thought that this was covered by having one SPL.
 - Both CM and PLDs must drug list. This is for tracking purposes, it is needed for a secure supply chain.
- CMs must use their own labeler code and their own NDC codes.
- If the PLD decides not to drug list, then the manufacturer has to request a labeler code and drug list on their behalf.
 - Not all companies know their own supply chain.
 - There may be legal issues with someone downstream listing for the company upstream (eg the API.)
 - A PLD may have to list to be reimbursed.
 - If a manufacturer is listing on behalf of the PLD, the PLD labeler and NDC codes must be included.
- Will the guidance be updated?
 - We are first tackling the 207 regulation.
- Would the PLD drug listing and the CM drug listing have to reference each other? If so, how?
 - Currently, there is no way to cross-reference this within the SPL.
 - Make sure that the registered establishment (CM) is included as a manufacturer in the PLD listing SPL – ie at the bottom of the SPL.

9. Issue Resolution when there are Import Issues:

When issues come up as a product is being imported, what should the sponsor do to resolve this as quickly as possible? Currently we work on the resolution of issues on a case by case basis.

Question: Who should we contact and/or what is the best process to follow when differences or issues come up?

- DRLS
- Import area
- Review division

Response Discussion - Import:

- We suggest that sponsors work as closely as possible with district office to resolve differences—compliance officer or investigator at the district who is handling the entry. The local FDA reviewer will have access to the most complete information and are in the best position to resolve the issue, even when it involves verification with CDER Office of Compliance. Also, any and all imports hearings will occur through the district office.
- CDER Office of Compliance Exports doesn't get involved until all the issues are identified and the field office receives a response or gets contacted by that district office or the Division of Import Operations and Policy. The FDA DRLS and Import Export offices can only provide an opinion. They won't have all the information that would enable them to respond in the context of the specific import instance.
- Per 21CFR 1.94, the district office has the ultimate authority over the import issue.
- Each importation is a separate instance. Previous resolution of a similar issue may not be relevant as import situations are highly variable, and foreign/domestic variables may have changed. If there is an SPL issue, the SPL needs to be fixed prior to any resolution. DRLS and Lonnie can help resolve the SPL problems.
- Huascar Batista is the FDA OC Import Export lead for CDER. His counterpart at CBER is Kimberly Cressotti.

Response/Discussion CVM – Veterinary Products:

Post meeting note:

The FDA OC Import contacts for CVM is Judy Baron and Jack Geltman

Response/Discussion by DRLS:

- DRLS office acts as consult only. They can provide information, but the district office has the authority to make the final decision.
- Your best plan is to contact the district person at the point of entry.
- It may be helpful to provide the Import Officer with a printout of what was submitted, what was accepted. The office can use that as a point of comparison with DRLS, Imports office, etc. When requested by the District, CDER will review the facts in concordance with the rest of the data provided for the product.
- If a compliance officer decides a product is subject to detention, when there is a compliance question the officer can request assistance Huascar Batista's office. They can review the information against the CDER information in total. All the information must be complete and correct.
 - how the product was declared
 - how the product was listed
 - manufacturers allowed in the application

- what is the inspection status
- compliance with 510 and regulations.
- Is the importer of record registered/known.

Other discussion:

- Suggestions for information to provide on importation documentation:
 - For affirmations of compliance at the port, the correct NDC numbers and registration number should be available.
 - Provide the correct NDC number and DUNS number in your import documents.
 - Drug Listing number should not be replaced with a DUNS number.
 - Using the DUNS number may be particularly helpful for newly approved drugs, that may not have an FEI number yet.
 - You can include both the FEI and DUNS number in the import documentation, so that the field import inspector has enough information to work with at importation.
- The importation officers use the OASIS system at ports of importation. Formerly called ISIS.
 - OASIS is an interface / system that allows the port and district office to access the information provided to customs for importation of products.
 - It is also the interface with FDA – ie to give FDA what it needs to review the import situation. Pulls the information from many different databases (primarily Customs).

10. Resolving issues related to DUNS information:

It appears that D&B information is now being referenced by FDA to a greater extent than in the past. Sponsors are finding that D&B information is not correct, and that D&B is creating/modifying records without direct communication with the company.

An issue arises when FDA rejects drug listing submissions because of incorrect D&B information. This is exacerbated when the incorrect data relates to a contract or foreign manufacturers. Sponsors do not have direct control or authority over third party or contract manufacturers. If D&B information for a third party or contract manufacturer is incorrect, a sponsor cannot fix the information at D&B. It could take a long time to evaluate and correct the situation. Meanwhile, the drug listing is being held up.

Request/question: Please provide direction on how a sponsor, in conjunction with the FDA, can solve this problem.

Response/Discussion by DLRS:

- FDA understands the issue, but the DUNS data needs to match. If it doesn't, the information must be corrected. This may take time to correct with Dunn and Bradstreet.
- FDA is using a Level 10 validation to verify the company name and DUNS number – not perfect, but close.
